March 1, 2001

Kate-Louise Gottfried, J.D. M.S.P.H
Executive Director
Office for Human Research Protections
Office of Public Health and Science, OS
6100 Executive Boulevard, Room 3B01 (MSC 7507)
Rockville, MD 20892-7507

Dear Ms. Gottfried:
Re: National Human Research Protection Advisory Committee Draft Interim Guidance on Financial Relationships in Clinical Research: Issues for Institutions, Clinical Investigators, and IRBs to Consider When Dealing With Issues of Financial Interests and Human Subject Protection

This letter presents the comments of the University of California Office of the President on the Draft Interim Guidance referenced above and issued on January 10, 2001.
The University of California shares your agency's concern about the effect of investigators and institutions financial interest in drugs or devices used in their conduct of human subject research. The University addresses this concern by developing comprehensive conflict of interest policies that designate institutional officials to administer, implement and enforce those policies, and continuously strives to strengthen the capacity of its IRBs to fulfill their role in this effort. In the Draft Interim Guidance under consideration, the National Human Research Protection Advisory Committee (NHRPAC, or the Committee) voices the same commitment held by the University to protect both human subjects as well as the integrity of the research process.

However, the Draft Interim Guidance appears overreaching or premature where it:
- attempts to address the issue of institutional conflicts of interest, an area for which regulations have not yet been set forth and which presently are the subject of examination within the University of California and among the higher education community (Section 4.1 of the Draft Interim Guidelines);
- requires an unreasonable level of expertise on the part of IRBs to monitor complex institutional conflicts of interest and imposes an overwhelming workload on them to serve as conflict management review boards, in addition to their current responsibilities (Sections 1.8 and 4.4 of the Draft Interim Guidelines); and
- generally fails to distinguish the conflicts of interest peculiar to clinical research from those that are specific to basic research.

The University would welcome instead an alternative approach to the Draft Interim Guidelines. We would participate in a conference with other members of the academic community and interested federal agencies to reach consensus on needed regulatory protections and policy development in the area of financial conflicts of interest and human subject protection.
We appreciate the opportunity to provide comments on NHRPAC's Draft Interim Guidance.
Sincerely,

s/ C. Judson King
C. Judson King
Provost and Senior Vice President
Academic Affairs